

FACTS V.1 - [Maintain Sample Collection]																					
<div style="display: flex; justify-content: space-between; align-items: center;"> Action Edit Options Related Info Navigate Tracing Window Help Page 1 2 </div>																					
<div style="display: flex; justify-content: space-between;"> <div> Sample Number: <input type="text" value="2355"/> </div> <div> Sample Class: <input type="text" value="Normal Everyday Sam"/> </div> <div> Sampling District: <input type="text" value="MIN-DO"/> </div> <div> Status: <input type="text" value="In Progress"/> </div> </div>																					
Collection Method: <input type="text" value="3 bottles collected at random from dealers stock, all of the same code"/>																					
State: <input type="text" value="MN"/>	County: <input type="text" value="CARLTON"/>	Country of Origin: <input type="text" value="United States"/>																			
Estimated Value: <input type="text" value="\$250.00"/>	Sample Cost: <input type="text" value="\$10.00"/>	Payment Method: <input type="text" value="Cash"/>	Receipt Issued: <input type="text" value="FDA484"/>																		
Carrier Name: <input type="text"/>	Date Shipped: <input type="text" value="10/01/1998"/>	Consumer Complaint Number: <input type="text"/>	Recall Number: <input type="text"/>																		
How Prepared: <input type="text" value="Each bottle label identified as below. Bottles packed together in cardboard box, identified as below, and officially sealed as below"/>																					
Collector's ID On Package/Document: <input type="text" value="2355 10-7-98 SHR"/>		Collector's ID On Seal: <input type="text" value="2355 10-7-98 Silvia H. Rogers"/>																			
Sample Delivered To: <input type="text" value="FED EX"/>		Sample Delivered Date: <input type="text" value="10/07/1998"/>																			
CR & Records Sent To: <input type="text" value="CHI-DO"/>	Storage Requirement: <input type="text" value="Ambient"/>																				
Dairy Permit Number: <input type="text"/>	Food Canning Establishment: <input type="text"/>		<input type="checkbox"/> 704 (d) Sample																		
National Drug Code: <input type="text"/>	CRx/DEA Schedule: <input type="text"/>		<input type="checkbox"/> 702 (b) Portion Collected																		
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> Collection PACs <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">PAC Code</th> <th style="width: 80%;">Description</th> <th style="width: 10%;"></th> </tr> </thead> <tbody> <tr> <td>56008A</td> <td>DRUG PROD SURVEILLANCE-BUR SAMPLING</td> <td style="text-align: center;">Add</td> </tr> <tr> <td> </td> <td> </td> <td style="text-align: center;">Delete</td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> </div> <div style="width: 45%;"> Sample Sent To <table border="1" style="width: 100%; border-collapse: collapse;"> <tbody> <tr> <td>NYK-RL</td> <td style="text-align: center;">Add</td> </tr> <tr> <td> </td> <td style="text-align: center;">Delete</td> </tr> <tr> <td> </td> <td> </td> </tr> </tbody> </table> </div> </div>				PAC Code	Description		56008A	DRUG PROD SURVEILLANCE-BUR SAMPLING	Add			Delete				NYK-RL	Add		Delete		
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56008A	DRUG PROD SURVEILLANCE-BUR SAMPLING	Add																			
		Delete																			
NYK-RL	Add																				
	Delete																				

Sample Flag Codes [X]

Find

Sample Flag Description

- 301(k) Sample
- Complaint Sample
- Dealer Voluntarily Holding
- Exhibit Sample
- Factory Food Sample
- Fumigated
- Inv. Samples of Fifth Exhibits
- Pesticide Sample
- Reconditioned
- Split Sample

Find OK Cancel

Sample Flag Codes [X]

Find

Sample Flag Description

- Exhibit Sample
- Factory Food Sample
- Fumigated
- Inv. Samples of Fifth Exhibits
- Pesticide Sample
- Reconditioned
- Split Sample
- Survey Sample
- Under State Embargo

Find OK Cancel

Sample Flags [X]

Sample Flags

Sample Flag	Remarks
Dealer Voluntarily	will voluntarily hold until 10-30-98

OK Add

FACTS Editor [X]

Dealer Voluntarily Holding

Fact Code: 54 A D A 03

Fact Name: Vit B2; Human N

Fact Label: in part: "SuperB 4

Search OK Cancel

des Sample

FACTS V.2														
Action	Edit	Options	Related Info	Navigate	Window	Help								
Sample Number:	2340		Sample Class:	Normal Everyday Sam		Sampling District:	CHI-DO		Status:	In Progress		Modif Count #:		
Collector:	Sylvia H. Rogers			Collection Date:	09/25/2000		Lot Size:	125 CS/12 BTLS/100 TAB						
Sample Origin:	Domestic			Sample Basis:	Compliance			Sample Type:	Documentary					
FIS Sample Number:	00	308358	Episode Number:		Related Sample:		Compliance Number:							
Sample Description: Sample consists of photographs and copies of records documenting interstate commerce and cGMP deficiencies for Willaprin Art														
Collection Reason: Collected during EI of dealer, dated 9/20-25/2000 to document interstate commerce and cGMP deviations. No analysis needed.														
Collection Remarks: See EIR of dealer and FDA-483, dated 9/20-25/2000 for more information. FDA-483 points 1-12 discuss deviations specific to th														
Associated Firms														
Resp Firm Type:	Dealer			FEI Number	B	Firm Type		Firm Name						
<input type="checkbox"/> Dealer is Consumer				3000901032	Dealer	Wilson Pharmaceutical, 300 S								
				3000901033	Ingredient Supplier	Woleske Chemical, 100 W. Me								
Product														
Product Code:	60	L	B	A	05	B	Brand Name:	Willaprin Arthritis Formula						
Product Name:	Aspirin (Analgesic); Human N/Rx Comb Ingr; Pi						Product Description:	Aspirin Non-Rx Combination Tablet						
Product Label:	Finished product is labeled in part: ****WILAPRIN ARTHRITIS FORMULA 500 Tablets***Active Ingredients: Acetylsalicylic Acid ... 5													
				Documents Obtained		Manufacturing Codes		Sample Flags						

FACTS V.2																					
Action	Edit	Options	Related Info																		
Navigation																					
Window Help																					
Sample Number: 2340		Sample Class: Normal Everyday Sam																			
Sampling District: CHI-DO		Status: In Progress																			
Modif Count #:																					
Collection Method: Copies of records collected during EI, dated 09/20-25/2000. Photographs taken 09/23/2000.																					
State: IL		County: COOK																			
Country of Origin: United States																					
Estimated Value: \$4500.00		Sample Cost: \$0.00																			
Payment Method: No Charge		Receipt Issued: None																			
Carrier Name: Roadway		Date Shipped: 06/06/1999																			
Consumer Complaint Number:		Recall Number:																			
How Prepared: All records and photographs identified as below and submitted to Supervisory Investigator. Negatives and extra photos placed in 52																					
Collector's ID On Package/Document: "DOC 2340 9/25/00 SHR"		Collector's ID On Seal: "DOC 2340 9/25/00 Sylvia H. Rogers"																			
Sample Delivered To:		Sample Delivered Date:																			
CR & Records Sent To: CHI-DO		Storage Requirement:																			
Dairy Permit Number:		Food Canning Establishment:																			
National Drug Code:		CRx/DEA Schedule:																			
Collection PACs		Physical Sample Sent To:																			
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">PAC Code</th> <th style="width: 65%;">Description</th> <th style="width: 20%;">Add</th> </tr> </thead> <tbody> <tr> <td>56002</td> <td>DRUG PROCESS INSPECTIONS(DPI)</td> <td style="text-align: center;">Add</td> </tr> <tr> <td> </td> <td> </td> <td style="text-align: center;">Add</td> </tr> <tr> <td> </td> <td> </td> <td style="text-align: center;">Delete</td> </tr> </tbody> </table>		PAC Code	Description	Add	56002	DRUG PROCESS INSPECTIONS(DPI)	Add			Add			Delete	<table border="1" style="width: 100%; border-collapse: collapse;"> <tbody> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> </tbody> </table>							
PAC Code	Description	Add																			
56002	DRUG PROCESS INSPECTIONS(DPI)	Add																			
		Add																			
		Delete																			

Sample Flags				
Sample Flags				
Sample Flag ▼	Remarks			
301(k) Sample				
				OK
				Add
				Delete

Documents Obtained				
Document				
Document Type ▼	Document Number	Document Date	Remarks	
Affidavit	1	09/25/2000	Affidavit signed by Robert Wilson, Presic	↑
Invoice	2	06/16/1999	Invoice no. 2346 dated 06/16/2000 from	
Bill of Lading	3	06/16/1999	Bill of Lading no. 124679 dated 06/16/200	↓
				OK
				Add
				Delete

Manufacturing Codes		
Manufacturing Codes		
Manufacturing Code	Exp Date	
"Lot 25C83" (Finished Product)	8/06	
"Batch 5564 "(Active Ingredient)	8/02	
		OK
		Add
		Delete